UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DIOMED, INC.

Plaintiff,

v.

VASCULAR SOLUTIONS, INC.

Defendant.

Civil Action No. 04-CV-10444-RGS

DEFENDANT VASCULAR SOLUTIONS, INC.'S RESPONSE TO DIOMED'S CLAIM CONSTRUCTION MEMORANDUM

INTRODUCTION

Defendant Vascular Solutions, Inc. ("VSI") respectfully submits this response to plaintiff Diomed, Inc.'s ("Diomed") claim construction memorandum. In its brief, Diomed raised the additional issue concerning the construction of Claim 9. VSI did not address Claim 9's requirement about the clinical effect of the method in its opening brief because VSI did not believe it was in dispute. Claim 9 requires "emitting said laser energy into the blood vessel . . . *thereby decreasing the diameter of said blood vessel*." Although Diomed's proposed construction is vague, Diomed's brief admits that this clinical effect must be caused by the delivery of laser energy to the blood vessel wall during intraluminal contact, and not by delivery of laser energy to the blood itself or by the clotting of blood. This Court should make that explicit in its construction of Claim 9. The Court should construe the claim limitation "thereby decreasing the diameter of said blood vessel" to require that the clinical effect must be caused by the delivery of laser energy to the blood vessel wall during intraluminal contact, and not by delivery of laser energy into the blood itself or by the use of laser energy to clot the blood.

For the reasons stated here and in VSI's October 1, 2004 claim construction memorandum ("VSI Oct. 1 Mem."), this Court should adopt the following constructions of the remaining claim limitations of Claim 9:

1) "means for emitting laser energy" means a fiber optic line with an uncoated, rounded tip and its equivalents.

2) "placing said laser emitting section . . . into intraluminal contact with the blood vessel" requires a deliberate act to "place" the uncoated rounded tip of the fiber optic line into physical contact with the interior blood vessel wall. The patent specification and file history further require construing "placing . . . into intraluminal contact" to mean draining the blood from the blood vessel and applying compression to the blood vessel to insure intraluminal contact.

3) "emitting said laser energy into the blood vessel" means delivery of the laser energy into the blood vessel wall during intraluminal contact.[1]

ARGUMENT

I. DEFENDANTS' CONSTRUCTION OF CLAIM 9 SHOULD BE ADOPTED

A. "inserting means for emitting laser energy into the blood vessel at a puncture site, wherein said emitting means has a laser emitting section"

Defendants VSI and AngioDynamics construe the "means for emitting laser energy" limitation to cover a fiber optic line with an uncoated, rounded tip and its equivalents. See VSI Oct. 1 Mem., pp. 8-9. Defendants' construction is based on well-settled law concerning the construction of means-plus-function limitations, as a fiber optic line with an uncoated, rounded tip is the only structure disclosed in the '777 Patent for performing the function of "emitting laser energy."

Diomed contends that this limitation should be construed to cover "any of the stand-alone fiber optic lines disclosed in the '777 patent specification" and equivalents. Diomed further

[1] As noted below, Diomed now agrees with VSI that "emitting said laser energy into the blood vessel wall" means delivery of laser energy into the blood vessel wall during intraluminal contact.

contends that the "exposed portion" of the fiber optic line, from which the laser energy is emitted, need not be the tip, and that the tip need not be rounded. See Diomed Oct. 1 Mem., pp. 11-14. Diomed advances its argument by artificially separating the phrase "wherein said emitting means has a laser emitting section" from the "means for emitting laser energy." Id., pp. 13-14.

Diomed's construction violates the fundamental principle of construction of means-plus-function claims. The Court must identify the specific *structure* disclosed in the patent specification for performing the stated function of "emitting laser energy." See Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1321 (Fed. Cir. 2003); Medtronic, Inc. v. Advanced Cardiovascular Systems, Inc., 248 F.3d 1303, 1311 (Fed. Cir. 2001). That structure must also be "closely linked" to the stated function in the patent specification. Medtronic, 248 F.3d at 1311.

Diomed cannot dispute that the *only structure* disclosed in the '777 Patent for "emitting laser energy" is a fiber optic line with an uncoated, rounded tip. See '777 Patent, Col. 4 (Vitt Dec. Ex. 1). Despite Diomed's vague invocation of other fiber optic lines without those features, the simple fact is that the '777 Patent does not disclose any *structure* for emitting laser energy other than a fiber optic line with an uncoated, rounded tip. No generic fiber optic lines are disclosed; no fiber optic lines with "exposed portions" at places other than the tip are disclosed; and no fiber optic lines with non-rounded tips are disclosed. Moreover, Diomed cannot dispute that the patent specification closely links the function of "emitting laser energy" with a fiber optic line with an uncoated, rounded tip. See id., Col. 4, l. 52-62 (stating that "Fiber optic line 40 has a tip 41 that is uncoated so as to allow emittance of laser energy . . . [and] the rounded tip 41 is preferred because it enables the operator to more easily control the amount of vein to be treated . . ."). The Court should therefore construe this limitation to require a fiber optic line with an uncoated, rounded tip.

Diomed attempts to escape this straightforward construction by separately construing the term "laser emitting section." Diomed's proposed construction defies logic and grammar. The limitation reads "inserting means for emitting laser energy into the blood vessel at a puncture site, wherein said emitting means has a laser emitting section." The "laser emitting section" is *part of* the "emitting means"; it is not some separate structure requiring a different construction. See Smiths Ind. Medical Sys. v. Vital Signs, Inc., 183 F.3d 1347, 1351, 1357-58 (Fed. Cir. 1999) (claim term "means for supplying gas *having* a hollow interior and first and second openings at opposite ends thereof" limited to double entry squeeze bags described in specification).

Diomed's invocation of the doctrine of "claim differentiation" also fails, because Diomed has misstated the law. The Federal Circuit has made clear that "claim differentiation" does not apply where a dependent claim calls out the structure of a means-plus-function limitation from an independent claim. See Medtronic, 248 F.3d at 1313. Thus Diomed's arguments concerning dependent claims 14 (regarding the laser emitting section being located "at a tip") and 15 (regarding the "rounded tip") are incorrect as a matter of law. As the Federal Circuit stated in Medtronic:

> It is settled law, however that independent claims containing means-plus-function limitations do not have the same literal scope as dependent claims reciting specifically the structure that performs the stated function. . . . "[The independent claim] remains broader than [the dependent claim]. Literally, [the independent claim] covers the structure described in the specification and equivalents thereof. [The dependent claim] does not literally cover equivalents . . ."

248 F.3d at 1313, quoting Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1538 (Fed. Cir. 1991).

This Court should therefore reject Diomed's construction and adopt Defendants' construction: this limitation covers a fiber optic line with an uncoated, rounded tip and its equivalents.

B. "placing said laser emitting section of said emitting means into intraluminal contact with the blood vessel at a treatment site"

Diomed apparently agrees that "placing said laser emitting section . . . into intraluminal contact with the blood vessel" requires a deliberate act. VSI and AngioDynamics gave Diomed clear notice of their proposed construction. See VSI and AngioDynamics' Proposed Interpretations (Vitt Dec. Exs. 10-11). Diomed has not disputed that construction, see Diomed Oct. 1 Mem., pp. 14-15, and that construction is consistent with the ordinary meaning of the word "placing" and the intrinsic record. This Court should therefore rule that "placing said laser emitting section . . . into intraluminal contact" requires a deliberate act to "place" the uncoated rounded tip of the fiber optic line into physical contact with the interior blood vessel wall.

Diomed does dispute Defendants' view that the "placing" limitation requires draining the blood from the blood vessel and applying compression to achieve intraluminal contact. Diomed argues that "there is no requirement that contact must be achieved in any particular way. . . . Contact can of course be achieved (and, in practice, is often achieved) in other ways." Diomed Oct. 1 Mem., p. 15.

Diomed is wrong. The person of ordinary skill in the art, reading the '777 Patent and file history, would understand that draining the blood and applying compression to the blood vessel are necessary to insure intraluminal contact, and would interpret this claim accordingly.

The intrinsic record on this issue is powerful, yet Diomed brushes aside the statements in the patent specification without any real discussion, and completely ignores the file history. The inventors, in the file history, described their *invention* as requiring draining the blood and applying compression to achieve intraluminal contact. The inventors used that argument to distinguish the Goldman Patent's method, involving the application of laser energy into the blood to cause blood clotting, from their method, involving the delivery of laser energy directly to the blood vessel wall during intraluminal contact. See '777 File History, pp. 83-84 (Vitt Dec.

Ex. 2). As VSI noted in its opening brief, the '777 Patent specification repeatedly states that draining of blood and applying compression is *important* to *insure* intraluminal contact. '777 Patent, Col. 5, l. 12-17 and l. 26-31, Col. 6, l. 9-13 and l. 42-46 (Vitt Dec. Ex. 1).

Given the clarity of the intrinsic record, the person of ordinary skill in the art would understand that "placing said laser emitting section . . . into intraluminal contact with the blood vessel" requires draining the blood from the blood vessel and applying compression to achieve intraluminal contact. Diomed states that "[C]ontact can of course be achieved (and, in practice, is often achieved) in other ways"—but Diomed does not offer any evidence for that assertion, nor does Diomed provide even one example of those "other ways."

It is worth stressing that the issue on claim construction is not what may or may not be theoretically possible, but rather what the claims mean in light of what the patent itself discloses and teaches to the public. Diomed cannot dispute that the '777 Patent and its file history do not disclose or even hint at any "other ways" to achieve intraluminal contact, other than draining the blood and applying compression. Indeed, the central point of the claimed method, as the inventors repeatedly stressed in the specification and file history, is to *avoid* delivery of laser energy into the blood itself to create blood clots, and to instead deliver laser energy directly to the blood vessel wall via intraluminal contact. Diomed cannot explain, and the patent and file history certainly do not explain, how the physician can avoid creating blood clots and how he or she can achieve the "intraluminal contact" central to the claimed method, if the blood is not drained and no compression is applied.

As VSI noted in its opening brief, the Federal Circuit has repeatedly construed claim limitations more narrowly than a dictionary definition might require, where the file history and the specification show that a narrower construction is warranted. See VSI Oct. 1 Mem., p. 12. The Federal Circuit has reaffirmed that approach as recently as September 30 of this year.

Astrazeneca AB v. Mutual Pharmaceutical Co., Inc., 2004 WL 2186672 (Fed. Cir. 2004). The statements in the '777 Patent specification and file history would be understood by a person of ordinary skill in the art as requiring draining the blood and applying compression to achieve intraluminal contact.[2] This Court should adopt Defendants' construction, and reject Diomed's.

C. "emitting said laser energy into the blood vessel through said laser emitting section of said emitting means, thereby decreasing the diameter of said blood vessel"

Based on Diomed's proposed interpretation of this limitation and discussions between counsel, VSI anticipated a dispute over the limitation "emitting said laser energy into the blood vessel. . . ." As VSI explained in its opening brief, this limitation should be construed to require delivery of the laser energy to the blood vessel wall during intraluminal contact. See VSI Oct. 1 Mem., pp. 14-18.

Diomed does not dispute this point, however, and indeed does not even directly address the "emitting said laser energy into the blood vessel" limitation. Diomed instead agrees with VSI that this limitation requires "emission-during-contact." Diomed Oct. 1 Mem., p. 17. Diomed's proposed interpretation, however, does not match what Diomed says in its brief, as it is silent on whether "emitting said laser energy into the blood vessel" requires delivery of laser energy to the blood vessel wall during intraluminal contact. Id., p. 18. This Court should adopt VSI's construction, and construe this limitation to require delivery of the laser energy to the blood vessel wall during intraluminal contact.

Diomed focuses on the last phrase of this limitation, concerning the clinical effect of the claimed method. That phrase reads: "thereby decreasing the diameter of said blood vessel."

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[2] Diomed's claim differentiation argument does not help Diomed. "Claim differentiation" is a helpful tool, but it cannot "serve to broaden claims beyond their meaning in light of the specification . . . and does not override clear statements of scope in the specification and the prosecution history." Toro Co. v. White Cons. Ind., Inc., 199 F.3d 1295, 1302 (Fed. Cir. 1999)(internal citation omitted).

Again, the critical issue for the Court is to construe this limitation not in the vague way proposed by Diomed, but instead to make it clear based on the obvious meaning of the term and the clear teachings of the specification and the file history.

Grammatically, "thereby" means that the clinical effect, "decreasing the diameter of said blood vessel", must be caused by "emitting said laser energy into the blood vessel." As discussed above, the parties now agree that this limitation requires delivery of laser energy into the blood vessel wall during intraluminal contact. As discussed at length in VSI's opening memorandum, the inventors repeatedly distinguished their method from the prior art method of delivering laser energy into the blood itself to cause blood clots. The Court should therefore construe the claim limitation "thereby decreasing the diameter of said blood vessel" to require that the clinical effect must be caused by the delivery of laser energy to the blood vessel wall during intraluminal contact, and not by delivery of laser energy into the blood itself or by the use of laser energy to clot the blood.

II. DEFENDANTS' CONSTRUCTION OF THE "EMPTYING THE BLOOD VESSEL" LIMITATION OF CLAIMS 10 AND 21 SHOULD BE ADOPTED

Diomed argues that the limitation "emptying the blood vessel" is merely a "process", requiring only the removal of "some" of the blood from the blood vessel. Diomed Oct. 1 Mem., p. 19. Diomed is wrong for several reasons.

First, Diomed's construction conflicts with the claim language and the structure of Claims 10 and 21. The '777 Patent, and Claims 10 and 21 in particular, do not describe a "process" that need only be started to practice the claimed method. Instead, these claims require the physician to *empty* the blood vessel *before* applying laser energy. Claim 10 requires "emptying the blood vessel *prior* to emitting said laser energy." Claim 21 requires the same result, as the "emptying the blood vessel" limitation is a sequential step in the claimed method

that must come before the emission of laser energy. See Combined Systems, Inc. v. Defense Technology Corp., 350 F.3d 1207, 1211-12 (Fed. Cir. 2003).

Second, Diomed's construction conflicts with the plain meaning of "emptying." As explained in VSI's opening brief and not disputed by Diomed, "emptying" means the "act of making empty" and "empty" means "containing nothing." (Vitt Dec. Ex. 8). Third, Diomed's construction conflicts with the patent specification. In accordance with the plain meaning of the term, the specification repeatedly specifies that the blood should be "drained" from the blood vessel, to insure intraluminal contact and to avoid the creation of blood clots. '777 Patent, Col. 4, l. 35-37, Col. 5, l. 10-15, Col. 6, l. 9-13, Col. 6, l. 43-45 (Vitt Dec. Ex. 1).

Finally, Diomed argues that the removal of "every last blood cell" is impossible, and therefore VSI's construction should be rejected. Diomed's point of course provides no support for its construction, that only "some" of the blood need be removed. Factually, Diomed may be correct, though there is no evidence in the record on the point. But as a matter of claim construction law, the plain meaning of the term chosen by the inventors and the clear teaching of the specification should govern. At a minimum, Diomed's construction should be rejected and the Court should require the removal of substantially all of the blood from the blood vessel.

III. DEFENDANTS' CONSTRUCTION OF CLAIM 19 SHOULD BE ADOPTED

Because Diomed does not specifically address this limitation, VSI will stand on its opening brief.

CONCLUSION

For the reasons stated here and in VSI's opening brief, VSI's proposed claim construction should be adopted and Diomed's should be rejected.

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Respectfully Submitted,

VASCULAR SOLUTIONS, INC.

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